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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,783	08/09/2005	Yuji Matsuzawa	10525.0014-00000	9334

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EXAMINER	
LIU, SAMUEL W	

ART UNIT	PAPER NUMBER
1656	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,783	MATSUZAWA ET AL.	
	Examiner	Art Unit	
	Samuel W. Liu	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-65* is/are pending in the application.

4a) Of the above claim(s) *2-44,46-48 and 50-65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,45,49 and 55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/9/05 and 1/10/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of claims

Claims 1-65 are pending.

The amendment filed 1/10/2005 which amends claims 1-65 has been entered.

Continuation data and priority

This application is a 371 application of PCT/JP03/08690 filed 7/9/2003. Acknowledgment is made of Applicants' claim for foreign priority based on an Application No. 2002-201856 filed 7/10/2002 in Japan.

Restriction/Restrictions

Applicant's election (filed 7/20/07) of Group 1, claims 1, 5, 9, 13, 17, 21, 25, 29, 33, 37, 41, 45, 49 and 55, and SEQ ID NO:2 for examination without traverse is acknowledged. Claims 2-4, 6-8, 10-12, 14-16, 18-20, 22-24, 26-28, 30-32, 34-36, 38-40, 42-44, 46-48, 50-54 and 56-65 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Claims 5, 9, 13, 17, 21, 25, 29, 33, 37 and 41 are drawn into non-elected amino acid sequence of SEQ ID NOs: 4, 6, 8, 10, 12, 14, 16, 18, 20 and 22, respectively; and thus, are withdrawn from further consideration as well. Therefore, claims 1, 45, 49 and 55 and SEQ ID NO:2 are under examination. In the restriction requirement Grouping, claim 55 was inadvertently omitted from Group I. It is noted that claim 55 is in Group 1 as the restriction requirement clearly states that Group 1 includes "a kit comprising the polypeptide".

IDS

The references cited in the IDS filed 8/9/05, the IDS filed 1/10/05 and the IDS 6/5/07 have been considered by Examiner.

Objections to specification

The disclosure is objected to because of the following informalities:

(1) The continuing data of this application should be updated.

(2) The disclosure at page 17, lines 1, 5, 8-9, and 11-12 where sets forth http://www.cbs.dtu.dk/services/SignalP, http://www.cbs.dtu.dk/services/TargetP, and http://psort.ims.u-tokyo.ac.jp/form2.html, and http://sosui.proteome.bio.tuat.ac.jp/cgi-bin/sosui.cgi?/sosuisignal/sosui- signal_submit.html), is objected to because it contains an embedded hyperlink and/or other form of browser-executable code in page 3, the forth paragraph. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Applicants may remove "http://" so that the hyperlinker becomes inactive, i.e., the content followed by Http:// can be and should be left behind; and thus, a browser will only interpret the rest of the URL as text.

(3) At page 34, line 9, "RACE" should be spelled out in full for the first instance of use; see also page 59, line 19-21, "PACAP", "GHRH", "CRF", "ATCH" "GRP", "PTH"; page 59, lines 25-26, "GRO", "NAP", "ENA", PF4" "IP10", "GCP", "MCP", HC14", "MIP" and "RANTES".

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 1, 45, 49 and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "substantially the same as the amino acid sequence..."; the recitation is unclear in the metes and bounds of the relationship between the claimed protein and SEQ ID NO:2 in terms of the claim language "*substantially the same as...*". The specification ambiguously defines this recitation based on "homology" (see the specification of this published application "US2006/0110384 A1", paragraph [0023]). However, even in view of this "definition," it remains unclear as to the intended relationship between the claimed peptide and SEQ ID NO:2.

Claim 1 is indefinite in the recitation of "represented by". According to Encarta dictionary (http://encarta.msn.com/dictionary_/represent.html), the term "represents" means to "be equivalent of something" or to "symbolize something". As such, it is unclear as to whether applicant intends for the amino acid sequence of the claimed protein to be limited to SEQ ID NO:2 or if the term is meant to encompass polypeptides that are equivalent to or symbolized by SEQ ID NO:2. If the latter, it is unclear as to how a skilled artisan would recognize the scope of said proteins that are equivalent to or symbolized by SEQ ID NO:2. It is suggested that applicant clarify the meaning of "represented by". Claims 45, 49 and 55, which depend from claim 1, are also rejected.

*Examiner note that the specification of this published application "US2006/0110384 A1"at [0035] defines the "partial peptide" as any peptide having a partial amino acid sequence.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or

with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written description

Claims 1, 45, 49 and 55 are rejected under 35 U.S.C. 112, first paragraph, written description, because the specification contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The factors considered in the Written Description requirement are (1) level of skill and knowledge in the art, (2) partial structure, (3) physical and/or chemical properties, (4) functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the (5) method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. MPEP §2163.

(1) Physical and/or chemical properties:

Claim 1 is directed to a genus of isolated proteins comprising a polypeptide which is substantially the same as the amino acid sequence or a partial sequence thereof, wherein "substantially the same as ..." (genus) defined in the specification reads on "homology to ...", e.g., the sequence having homology of about 60% to SEQ ID NO:2 (see the specification of this published application "US2006/0110384 A1", paragraph [0023]). Herein, "homology" is not identical to but broader than the "sequence identity" (see [0072]), and wherein the "partial peptide" is "partial amino acid sequence" of the full-length SEQ ID NO:2 (see the specification

of this published application "US2006/0110384 A1", paragraph [0035]). It is noted that the claimed protein is unlimited with respect to function or activity.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as be structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." University of California v. Eli Lilly and Co., 1997 U.S. App. LEXIS 18221, at *23, quoting Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe a genus of genetic material, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these.

While the specification teaches that the polypeptide of SEQ ID NO:2, i.e., SST20-14, has a motif which can bind to lipid of lipoprotein (see the specification of this published application "US2006/0110384 A1", paragraph [0613]) and regulates adipocytes differentiation (claim 49), e.g., regulating mouse preadipocyte 3T3-L1 cell differentiation (see the specification of this published application "US2006/0110384 A1", paragraphs [0610], [0617-1618] and [0619-0620]), the specification, however, does not describe the structure or amino acid sequence for said motif and/or for the regulation thereof.

The art in the related field (Gombart et al. (*Blood* (2002) 99, 1332-1340) teaches that deletion mutations of an adipocytes regulation protein called CCAAT/enhancer binding protein, i.e., C/EBPα (see abstract) abrogate its transcriptional activation activity (see abstract and Table 3), suggesting that the partial sequence derived from the deletion or truncation cannot retain the biological activity of the full-length protein. The specification neither provides representative species to describe the "partial sequence" or the sequence which is substantially homologue to the instant SEQ ID NO:2 which has the above-discussed activity/function, nor provides animal model for the disclosed pharmaceutical composition (claims 45 and 49) comprising (i) the polypeptide of SEQ ID NO:2 or (ii) the "partial peptide" or (iii) the variant sequence substantially homologue to SEQ ID NO:2 wherein (i), (ii) or (iii) is used as a prophylactic (preventive) and/or therapeutic agent for disease involving abnormal adipocytes differentiation (claim 49). Both the art in related filed and the instant disclosure fail to teach this regard. Therefore, applicants are not in possession of the claimed amino acid sequence comprising variant polypeptide or oligopeptide which is the partial sequence of the full-length SEQ ID NO:2 (claim 1), the pharmaceutical composition (claims 45 and 49) and the kit (claim 55) comprising the sequence thereof.

(2) Partial structure

The claim language: "partial peptide", i.e., partial sequence" (see the specification of this published application "US2006/0110384 A1", paragraph [0035]) is a fragment or a portion of SEQ ID NO:2. The specification provides no representative species, i.e., structure of the disclosed "partial peptide" nor working example for structure and function relationship of the partial sequence.

(3) Level of skill and knowledge in the art:

The level of skill in this art is high. The variants encompassing the partial sequence or/and subsequence substantially the same as the full-length SEQ ID NO:2 may be inactive (see the above Gombart et al. teaching). Thus, the result of screening for and characterization of the functional protein thereof is not predictable. Given no disclosure of structural species described in the specification and the unpredictability of the art, applicants have failed to adequately describe enough representative species of the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Scope enablement

Claims 1, 45, 49 and 55 are rejected under 35 U.S.C. 112, first paragraph, because the specification while being enabling for the isolated protein of SEQ ID NO:2 and a composition thereof, does not reasonably provide enablement for all proteins encompassed by the claims and the pharmaceutical composition and kits thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in Ex parte Form, 230 USPQ 546(BPAI 1986). They include the nature of the invention, the state of the art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

(1) The scope of the claims/(2)The nature of the invention:

The claims are directed to the isolated variant polypeptide/peptide which is substantially the same as the amino acid sequence or a partial sequence (claim 1), wherein "substantially the same as ..." (genus) defined in the specification reads on "homology to ...", e.g., the sequence having homology of about 60% to SEQ ID NO:2 (see the specification of this published application "US2006/0110384 A1", paragraph [0023]), wherein "homology" is not identical to but broader than "sequence identity" (see the specification of this published application "US2006/0110384 A1", paragraph [0072]), and wherein the "partial peptide" is "partial amino acid sequence" of the full-length SEQ ID NO:2 (see the specification of this published application "US2006/0110384 A1", paragraph [0035]). The variant polypeptide or oligopeptide (genus) encompasses enormous variant species resulted from deletion, truncation, substitution and/or insertion. The specification does not teach that the variant polypeptide or oligopeptide has the activity of the full-length sequence of SEQ ID NO:2, nor provides working examples thereof, and the claims do not require that the claimed protein have any particular function or activity. Also, the specification fails to provide the working example or animal model for the claimed pharmaceutical composition comprising the polypeptide of SEQ ID NO:2 or the variant molecule thereof, and for the kit comprising the variant molecule thereof; where the scope of pharmaceutical composition is so broad as to prevent (prophylactic) or treat any disease involving abnormality of adipocytes differentiation and/or metabolism function.

(3) The unpredictability of the art:

While the specification teaches that the polypeptide of SEQ ID NO:2, i.e., SST20-14, has a motif which can bind to lipid of lipoprotein (see the specification of this published application "US2006/0110384 A1", paragraph [0613]) and regulates adipocytes differentiation

(claim 49), e.g., regulating mouse preadipocyte 3T3-L1 cell differentiation (see the specification of this published application "US2006/0110384 A1", paragraphs [0023] [0610], [0617-1618] and [0619-0620]), the specification fails to teach the structure of said motif and/or for the regulation thereof. Gombart et al. (*Blood* (2002) 99, 1332-1340) teach that deletion mutations of an adipocytes regulation protein called CCAAT/enhancer binding protein, i.e., C/EBPα (see abstract) abrogate its transcriptional activation activity (see abstract and Table 3). This suggests that the partial sequence derived from the deletion or truncation cannot retain the biological activity of the full-length protein and is inactive, and that the result of screening for and characterization of the functional protein is unpredictable. In addition, the consequence of using the pharmaceutical composition as a "prophylactic" (preventive) and/or therapeutic agent for preventing/treating any disease involving abnormality of adipocytes differentiation and/or metabolism function is not predictable, because of the unpredictability of the protein which constitute the pharmaceutical composition (see the above discussion), and because the specification does not teach how to extrapolate data obtained from study of the full-length SEQ ID NO:2 protein having effect on the abnormal adipocytes differentiation and/or metabolism to the prevention of any diseases and/or development of therapeutic agent to treat any diseases involving said abnormality.

(4) The state of the prior art:

The art in related field does not teach or provide factual indicia that the variant polypeptide or oligopeptide (see above) has the biological function of SEQ ID NO:2, nor teach that the pharmaceutical composition formulated with the polypeptide of SEQ ID NO:2 having property of preventing disease sate associated with abnormal adipocytes differentiation (claim

49) or the polypeptide structurally closed related thereof, or having the ability to treat any diseases involving the above discussed abnormality.

(5) The quantity of experimentation necessary:

In the absence of working examples and/or teachings with regard to the above discussed variant polypeptide or oligopeptide having the function of the full-length sequence and the pharmaceutical composition comprising the variant molecule thereof, it would take undue trials and errors to practice the claimed invention. The quantity of experimentation is thus large.

(6) The relative skill of those in the art:

The general knowledge and level of skill in the art is high and requires at least a biochemist with several years of experience in recombinant DNA technology, pharmacology, protein chemistry, protein purification as well as knowledge in medicine in the relative fields, e.g., treatment of obesity and diabetes (see the specification of this published application "US2006/0110384 A1", paragraphs [0164] and [0169]).

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view of the quantity of experimentation necessary the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention. Thus, the amount and level of experimentation needed is undue.

Claim Rejections - 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

• Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Wood et al. (WO 9914328).

In patent claim 12, Wood et al. teach an isolated polypeptide comprising SEQ ID NO:310 (see Figure 108) which has 90.4% sequence identity to instant SEQ ID NO:2 (see the attachment 1), which anticipate instant claim 1.

• Claims 1, 45, 49 and 55 are rejected under 35 U.S.C. 102(e) as being anticipated by Goddard et al. et al. (US Pat. No. 7189807 B2).

Goddard et al. teach the isolated polypeptide comprising SEQ ID NO:370 (see Figure 370, col. 24, col. 97, lines 31-59) which has 90.4% sequence identity to instant SEQ ID NO:2 (see the attachment 2). The polypeptide is isolated because SEQ ID NO:370 is encoded by isolated cDNA clone (col. 119, line 36-37), i.e., DNA40982-1235 (col. 23, lines 65-68, and

Example 4, col. 122, line 5), and because Goddard et al. teach the polypeptide is recombinantly isolated (col. 4, lines 57-59). Thus, Goddard et al. teach instant claim 1.

Goddard et al. teach a pharmaceutical composition comprising PRO polypeptide (col. 6, lines 14-19) which is encoded by PRO332 cDNA, i.e., PRO332 polypeptide, which consists of SEQ ID NO:332 (Figure 370, col. 24, lines 1-3). The Goddard et al. teachings anticipate instant claim 45.

Since the recitation of claim 49 "which is a prophylactic and/or therapeutic agent for disease ..." is considered to be an intended use which has little patentable weight, the above Goddard et al. teachings anticipate instant claim 49.

Claim 55, reciting a kit, as written, contains no positive recitation of the ingredients which distinguishes it over the references; therefore, the kit (a composition) is encompassed by the Goddard reference.

Claim Rejections - 35 USC §103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wood et al. (WO 9914328) in view of Ali et al. (US 20020037540 A1).

The rejection of claim 1 by Wood et al. has been discussed above.

Yet, Wood et al. do not expressly teach a kit comprising the polypeptide.

At [0150], Ali et al. teach a kit comprising a polypeptide useful for identifying ligand, agonist or antagonist for said polypeptide, as applied to claim 55.

*Examiner note: while the claim recites a kit, no positive recitation of the ingredients distinguishes it over the references; therefore, the kit is encompassed by the Wood reference. However, in the event of that this is not the case, the 103(a) rejection below is applicable to claim 55 herein.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate the kit comprising the full-length polypeptide of instant SEQ ID NO:370. This is because the polypeptide of SEQ ID NO:370 (also called: PRO332 polypeptide, see page 107, line 27) taught by Wood et al. is useful for identifying its ligand, e.g., receptor-ligand interaction (see page 98, lines 28-36), and because Ali et al. have taught that the kit developed is useful for the same purpose, i.e., identifying the ligand for said polypeptide. Moreover, it is a well known convention in the art to place these components in a pack or kit for convenience and economy. Therefor, in order to conveniently screening for the ligand including agonist, antagonist or/and receptor of said polypeptide, one skilled in the art would have constructed the

kit comprising the polypeptide according to the above references' teachings with reasonable expectation of success. Therefore, the claimed invention was *prima facie* obvious to make and use the invention at the time it was made.

Conclusion

No claims are allowed.

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:30 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

Samuel Wei Liu, Ph.D.
Patent Examiner, Art Unit 1656
August 14, 2007

/David J. Steadman/
David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656

10520783

102(b)

Attachment 1.

<!--StartFragment-->RESULT 2
AAY13396
ID AAY13396 standard; protein; 642 AA.
XX
AC AAY13396;
XX
DT 25-JUN-1999 (first entry)
XX
DE Amino acid sequence of protein PRO332.
XX
KW Secreted protein; transmembrane protein; human; enterocolitis;
KW Zollinger-Ellison syndrome; gastrointestinal ulceration;
KW congenital microvillus atrophy; skin disease; cell growth;
KW abnormal keratinocyte differentiation; psoriasis; epithelial cancer;
KW Parkinson's disease; Alzheimer's disease; ALS; neuropathy; fibromodulin;
KW dermal scarring; Usher Syndrome; Atrophia areata; anti-thrombotic;
KW wound healing; tissue repair.
XX
OS Homo sapiens.
XX
PN WO9914328-A2.
XX
PD 25-MAR-1999.
XX
PF 16-SEP-1998; 98WO-US019330.
XX
PR 17-SEP-1997; 97US-0059113P.
PR 17-SEP-1997; 97US-0059115P.
PR 17-SEP-1997; 97US-0059117P.
PR 17-SEP-1997; 97US-0059119P.
PR 17-SEP-1997; 97US-0059121P.
PR 17-SEP-1997; 97US-0059122P.
PR 17-SEP-1997; 97US-0059184P.
PR 18-SEP-1997; 97US-0059263P.
PR 18-SEP-1997; 97US-0059266P.
PR 15-OCT-1997; 97US-0062125P.
PR 17-OCT-1997; 97US-0062285P.
PR 17-OCT-1997; 97US-0062287P.
PR 21-OCT-1997; 97US-0063486P.
PR 24-OCT-1997; 97US-0062814P.
PR 24-OCT-1997; 97US-0062816P.
PR 24-OCT-1997; 97US-0063045P.
PR 24-OCT-1997; 97US-0063120P.
PR 24-OCT-1997; 97US-0063121P.
PR 24-OCT-1997; 97US-0063127P.
PR 24-OCT-1997; 97US-0063128P.
PR 27-OCT-1997; 97US-0063327P.
PR 27-OCT-1997; 97US-0063329P.
PR 28-OCT-1997; 97US-0063541P.

PR 28-OCT-1997; 97US-0063542P.
PR 28-OCT-1997; 97US-0063544P.
PR 28-OCT-1997; 97US-0063549P.
PR 28-OCT-1997; 97US-0063550P.
PR 28-OCT-1997; 97US-0063564P.
PR 29-OCT-1997; 97US-0063435P.
PR 29-OCT-1997; 97US-0063704P.
PR 29-OCT-1997; 97US-0063732P.
PR 29-OCT-1997; 97US-0063734P.
PR 29-OCT-1997; 97US-0063735P.
PR 29-OCT-1997; 97US-0063738P.
PR 29-OCT-1997; 97US-0064215P.
PR 31-OCT-1997; 97US-0063870P.
PR 31-OCT-1997; 97US-0064103P.
PR 03-NOV-1997; 97US-0064248P.
PR 07-NOV-1997; 97US-0064809P.
PR 12-NOV-1997; 97US-0065186P.
PR 17-NOV-1997; 97US-0065846P.
PR 18-NOV-1997; 97US-0065693P.
PR 21-NOV-1997; 97US-0066120P.
PR 21-NOV-1997; 97US-0066364P.
PR 24-NOV-1997; 97US-0066453P.
PR 24-NOV-1997; 97US-0066466P.
PR 24-NOV-1997; 97US-0066511P.
PR 24-NOV-1997; 97US-0066770P.
PR 24-NOV-1997; 97US-0066772P.
PR 25-NOV-1997; 97US-0066840P.
XX
PA (GETH) GENENTECH INC.
XX
PI Wood WI, Gurney AL, Goddard A, Pennica D, Chen J, Yuan J;
XX
DR WPI; 1999-229533/19.
DR N-PSDB; AAX52267.
XX
PT New isolated human genes and polypeptides used in, e.g. treatment of
PT gastrointestinal ulceration.
XX
PS Claim 12; Fig 108; 320pp; English.
XX
CC AAY13344-403 represent secreted and transmembrane human proteins. The
CC cDNA sequences are obtained from cDNA libraries, prepared from fetal
CC lung, fetal kidney, fetal brain, fetal liver and fetal retina. The
CC encoded polypeptides have specific uses based on their homology to known
CC polypeptides, e.g. PRO211 and PRO217 can be used for disorders associated
CC with the preservation and maintenance of gastrointestinal mucosa and the
CC repair of acute and chronic mucosal lesions (e.g. enterocolitis,
CC Zollinger-Ellison syndrome, gastrointestinal ulceration and congenital
CC microvillus atrophy), skin diseases associated with abnormal keratinocyte

CC differentiation (e.g. psoriasis, epithelial cancers such as lung squamous
CC cell carcinoma of the vulva and gliomas), potent effects on cell growth
CC and development, diseases related to growth or survival of nerve cells
CC including Parkinson's disease, Alzheimer's disease, ALS, neuropathies or
CC cancer. PRO265 can be used as for fibromodulin, e.g. for reducing dermal
CC scarring. PRO264 can be used as a target for anti-tumor drugs. PRO533 may
CC be used in the treatment of Usher Syndrome or Atrophia areata; PRO269 can
CC be used as an anti-thrombotic agent; PRO287 polypeptides and portions may
CC have therapeutic applications in wound healing and tissue repair; PRO317
CC can be used for treating problems of the kidney, uterus, endometrium,
CC blood vessels, or related tissue, e.g. in the heart of genital tract
XX
SQ Sequence 642 AA;

Query Match 90.4%; Score 2839; DB 2; Length 642;
Best Local Similarity 91.2%; Pred. No. 4e-230;
Matches 561; Conservative 23; Mismatches 25; Indels 6; Gaps 3;

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Qy          1 MAGSRGLPLLLLV-LQLFLGPVLPVRAPVFGRSDTPTLSPEENEFVEEENQPVLVLSSEE 59
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Db         30 MAQSRVLLLLLLLPPQLHLGPVLAVRAPGFGRSGGHSLSPEENEFAEEE--PVLVLSPEE 87

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Qy        120 LQRLETLNLQNNRLTSRGLPEEAFEHLTSLNYLYLANNKLTLAPRFLPNALISVDFAANY 179
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Db        148 LHRLETLNLQNNRLTSRGLPEKAFEHLTNLNYLYLANNKLTLAPRFLPNALISVDFAANY 207

Qy        180 LTKIYGLTFGQKPNLRSVYLHNNKLADAGLPDHMFNGSSNVEILILSSNFLRHVPKHLPP 239
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Db        208 LTKIYGLTFGQKPNLRSVYLHNNKLADAGLPDNMFNGSSNVEVLILSSNFLRHVPKHLPP 267

Qy        240 ALYKLHLKNNKLEKIPPGAFSELSNLRELYLQNNYLTDEGLDNETFWKLSSLEYLDLSST 299
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Db        268 ALYKLHLKNNKLEKIPPGAFSELSSLRELYLQNNYLTDEGLDNETFWKLSSLEYLDLSSN 327

Qy        300 NLSRVPAGLPRSLVLLHLEKNAIQSVEADVLTPIRNLEYLLLHSNQLQAKGIHPLAFQGL 359
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Db        388 KRLHTVHLYNNALERVPSGLPRRVRTLMILHNQITGIGREDFATTYFLEELNLSYNRITS 447

Qy        420 PQMHRDAFRKLRLLRSLDLSGNRLQTLPPGLPKNVHVLKVKRNELAALARGALAGMAQLR 479
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2y          480 ELYLTGNRLRSRALGPRAWVDLAGLQLLDIAGNQLTEVPEGLPPSLEYLYLQNNKISAVP 539
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Db          508 ELYLTSNRLRSRALGPRAWVDLAHLQLLDIAGNQLTEIPEGLPESLEYLYLQNNKISAVP 567

2y          540 ANAFDSTPNLKGIFLRFNKLAVGSVVESAFRRLKHLQVLDIEGNFEFGNGSKDK---DEE 596
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2y          597 EEEEEEEEDEEEETR 611
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Db          628 KEEEEEEEEEEEETR 642
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attachment 2.

<!--StartFragment-->RESULT 15
US-10-142-763-370
; Sequence 370, Application US/10142763
; Patent No. 7189807
; GENERAL INFORMATION:
; APPLICANT: Baker,Kevin P.
; APPLICANT: Beresini,Maureen
; APPLICANT: DeForge,Laura
; APPLICANT: Desnoyers,Luc
; APPLICANT: Filvaroff,Ellen
; APPLICANT: Gao,Wei-Qiang
; APPLICANT: Gerritsen,Mary E.
; APPLICANT: Goddard,Audrey
; APPLICANT: Godowski,Paul J.
; APPLICANT: Gurney,Austin L.
; APPLICANT: Sherwood,Steven
; APPLICANT: Smith,Victoria
; APPLICANT: Stewart,Timothy A.
; APPLICANT: Tumas,Daniel
; APPLICANT: Watanabe,Colin K
; APPLICANT: Wood,William
; APPLICANT: Zhang, Zemin
; TITLE OF INVENTION: SECRETED AND TRANSMEMBRANE POLYPEPTIDES AND NUCLEIC
; TITLE OF INVENTION: ACIDS ENCODING THE SAME
; FILE REFERENCE: P3330R1C243
; CURRENT APPLICATION NUMBER: US/10/142,763
; CURRENT FILING DATE: 2002-05-10
; Prior Application removed - See File Wrapper or Palm
; NUMBER OF SEQ ID NOS: 550
; SEQ ID NO 370
; LENGTH: 642
; TYPE: PRT
; ORGANISM: Homo Sapien
US-10-142-763-370

Query Match 90.4%; Score 2839; DB 3; Length 642;
Best Local Similarity 91.2%; Pred. No. 4.8e-249;
Matches 561; Conservative 23; Mismatches 25; Indels 6; Gaps 3;

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Qy          1 MAGSRGLPLLLLV-LQLFLGPVLPVRAPVFGRSDTPTLSPEENEFVEEENQPVLVLSSEE 59
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Db         30 MAQSRVLLLLLLLPPQLHLGPVLAVRAPGFGRSGGHSLSPEENEFAEEE--PVLVLSPEE 87

Qy         60 PEPGPATVDCPRDCACSQEGVVDCGGIDLREFPGDLPEHTNHLSLQNNQLEKIYPEELSR 119
              | |||| | ||||||||||||||||||||||||||||||||||||||||||||||||||
Db         88 PGPGPAAVSCPRDCACSQEGVVDCGGIDLREFPGDLPEHTNHLSLQNNQLEKIYPEELSR 147

Qy        120 LQRLETLNLQNNRLTSRGLPEEAFEHLTSLNYLYLANNKLTLAPRFLPNALISVDFAANY 179
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```
Db          148 LHRLETLNLQNNRLTSRGLPEKAFEHLTNLNYLYLANNKLTLAPRFLPNALISVDFAANY 207

Qy          180 LTKIYGLTFGQKPNLRSVYLHNNKLADAGLPDHMFNGSSNVEILILSSNFLRHVPKHLPP 239
                |||||||||||||||||||||||||||||||:|||||||||:||||||||||||||||||
Db          208 LTKIYGLTFGQKPNLRSVYLHNNKLADAGLPDNMFNGSSNVEVLILSSNFLRHVPKHLPP 267

Qy          240 ALYKLHLKNNKLEKIPPGAFSELSNLRELYLQNNYLTDEGLDNETFWKLSSLEYLDLSST 299
                |||||||||||||||||||||||:|||||||||||||||||||||||||||||||||||
Db          268 ALYKLHLKNNKLEKIPPGAFSELSSLRELYLQNNYLTDEGLDNETFWKLSSLEYLDLSSN 327

Qy          300 NLSRVPAGLPRSLVLLHLEKNAIQSVEADVLTPIRNLEYLLLHSNQLQAKGIHPLAFQGL 359
                |||||||||||||||||||||||:||:|:||||||:||||||||||: :||||||||||
Db          328 NLSRVPAGLPRSLVLLHLEKNAIRSVDANVLTPIRSLEYLLLHSNQLREQGIHPLAFQGL 387

Qy          360 KKLHTVHLYNNALERVPSGLPRRVRTLMILHNQITGIGREDFATTYFLEELNLSYNRITS 419
                |:|||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          388 KRLHTVHLYNNALERVPSGLPRRVRTLMILHNQITGIGREDFATTYFLEELNLSYNRITS 447

Qy          420 PQMHRDAFRKLRLLRSLDLSGNRLQTLPPGLPKNVHVLKVKRNELAALARGALAGMAQLR 479
                ||:|||||||||||||||||||| |||||||:||||||||||||||||||||||||||||
Db          448 PQVHRDAFRKLRLLRSLDLSGNRLHTLPPGLPRNVHVLKVKRNELAALARGALAGMAQLR 507

Qy          480 ELYLTGNRLRSRALGPRAWVDLAGLQLLDIAGNQLTEVPEGLPPSLEYLYLQNNKISAVP 539
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Db          508 ELYLTSNRLRSRALGPRAWVDLAHLQLLDIAGNQLTEIPEGLPESLEYLYLQNNKISAVP 567

Qy          540 ANAFDSTPNLKGIFLRFNKLAVGSVVESAFRRLKHLQVLDIEGNFEFGNGSKDK---DEE 596
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Db          568 ANAFDSTPNLKGIFLRFNKLAVGSVVDSAFRRLKHLQVLDIEGNLEFGDISKDRGRLGKE 627

Qy          597 EEEEEEEEDEEEETR 611
                :|||||||:||||||
Db          628 KEEEEEEEEEEEETR 642
```

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